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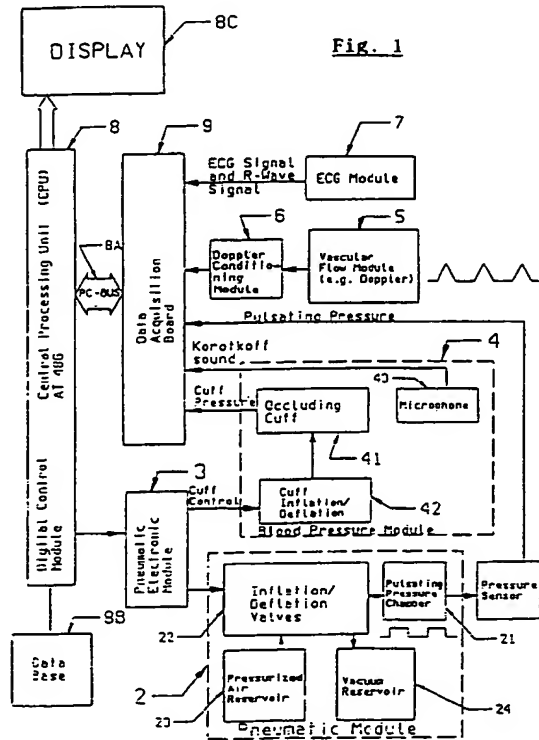
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<p> (30) Priority: 08.11.93 IL 10754093 (43) Date of publication of application: 10.05.95 Bulletin 95/19 (84) Designated Contracting States: DE FR GB IT </p>	<p> (71) Applicant: ROBIN MEDICAL TECHNOLOGIES LTD. Science Park Technion - Nesher, P.O. Box 212 Nesher 36601 (IL) (72) Inventor: Nevo, Erez 9 Keren Hayesod Street Kiryat Bialik 27000 (IL) (74) Representative: Modiano, Guido, Dr.-Ing. et al Modiano, Josif, Pisanty & Staub, Baaderstrasse 3 D-80469 München (DE) </p>
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(54) **Method and apparatus for assessing cardiovascular performance.**

(57) A method of assessing the cardiovascular performance of a subject, by: applying periodically, in synchronism with every n^{th} heart cardiac cycle wherein "n" is at least two, external pressure pulsations on a peripheral organ of the subject sufficient to alter ventricular loading; acquiring data representative of the ventricular pressure, and data representative of the ventricular volume, of the subject's heart over a plurality of heart cardiac cycles; and utilizing such data for assessing the cardiovascular performance of the subject. Ventricular loading may be altered by impeding ventricular ejection (changing afterload), and/or by altering venous return to the heart (changing preload).



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The present invention relates to a method and apparatus for assessing the cardiovascular performance of a subject, particularly for diagnosing and/or monitoring treatment of patients with ischemic heart diseases (IHD) or with heart failure (HF).

US Patent 4,877,035, which is hereby incorporated by reference, discloses a technique for determining the end-systolic elastance (Ees) of a subject's heart. Ees is generally accepted as an index of myocardial contractility, a characteristic very useful in assessing the cardiovascular performance of the subject. As described in this patent, Ees is determined by measuring the end-systolic pressure-volume relation in which the afterload is varied by the controlled inflation of an intraaortic balloon catheter positioned in the ascending aorta. Balloon inflation is timed to transiently interrupt ventricular ejection at different times during the ejection phase, producing contraction at different ventricular volumes. Simultaneous measurements of left ventricular pressure and aortic volume during the occlusion sequence allows pressure vs. ejected volume loops to be generated, from which the slope of the end-systolic pressure-volume relationship can be determined.

The technique described in the above patent, however, is extremely limited in clinical practice because of the complex invasive procedure required, namely the introduction and controlled inflation of the intraaortic balloon.

An object of the present invention is to provide a novel, non-invasive method, and also an apparatus, for assessing the cardiovascular performance of a subject.

According to the present invention, there is provided a method of assessing the cardiovascular performance of a subject, comprising: applying periodically, in synchronism with every n^{th} heart cardiac cycle wherein "n" is at least two, external pressure pulsations on a peripheral organ of the subject sufficient to alter ventricular loading; acquiring data representative of the ventricular pressure, and data representative of the ventricular volume, of the subject's heart over a plurality of heart cardiac cycles; and utilizing the data for assessing the cardiovascular performance of the subject.

The ventricular loading may be altered by impeding ventricular ejection (changing afterload), and/or by altering venous return (changing preload).

The invention also provides apparatus for assessing the cardiovascular performance of a subject in accordance with the above method.

As will be described more particularly below, the method and apparatus can be implemented in a fully non-invasive manner thereby greatly extending its potential use in routine clinical practice.

Fig. 1 is a block diagram illustrating the main components of one form of apparatus constructed in accordance with the present invention;

Fig. 2 is a diagram illustrating the determinants of the cardiovascular system performance;

Fig. 3 illustrates a series of waveforms showing the effects of external pressure pulsations as applied in accordance with one described embodiment of the invention;

Figs. 4A and 4B are waveforms illustrating the aortic flow during the performance of the assessment method in accordance with the present invention, and Fig. 4C illustrates the resultant ventricular volume;

Figs. 5A and 5B illustrate a technique for reconstructing a pressure wave;

Figs. 6A and 6B illustrate the technique of Figs. 5A and 5B for reconstructing the pressure waves in accordance with the present invention; Fig. 7A illustrates the manner of reconstructing the pressure-volume loop in the method described herein;

Fig. 7B illustrates the manner of determining the ESPVR (end-systolic pressure volume relation) in the described method, to provide an accepted approximation of the ventricular elastance of the subject's heart;

Fig. 8 illustrates a series of waveforms showing the effects of external pressure pulsations as applied in accordance with another described embodiment of the invention;

and Fig. 9 illustrates the manner of reconstructing the pressure-volume loop in the embodiment illustrated in Fig. 8.

The apparatus illustrated in Fig. 1 comprises a pneumatic module, generally designated 2, which applies external pressure pulsations to a peripheral organ of a subject, such as a limb (e.g., arm or leg) or the lower abdomen, sufficient to alter ventricular loading. The pneumatic module 2 is controlled by an electronic control module 3, as will be described more particularly below.

The illustrated apparatus also includes a blood pressure module 4 which measures the blood pressure of the subject; a vascular flow module 5, and a Doppler conditioning module 6, for measuring the aortic flow rate of the subject; and an ECG module 7 which detects the ECG signal of the subject's heart. The external pressure pulsations applied by the pneumatic module 2 are synchronized with the heart cardiac cycle, as will be described more particularly below.

All the foregoing modules are controlled by a data processor including a central processing unit (CPU) 8, which communicates directly with the pneumatic control module 3, and with the other modules via a data acquisition board 9 and a PC bus 8a. The CPU 8 is supplied with data from a

database 8b, and controls a display 8c.

The pneumatic module 2 applies pulsating external pressures on the lower body (e.g., lower limb and/or abdomen) via a pulsating pressure chamber unit 21. The latter unit includes a plurality of pressurized chambers incorporated in a pressure suit or pressure cuff(s) to be applied to the body. The pulsating pressure chamber unit 21 communicates, via an inflation/deflation valve unit 22, with a pressurized air reservoir 23 and with a vacuum reservoir 24. Valve unit 22 includes a valve for each chamber connecting the respective chamber either to the pressurized air reservoir 23 for inflating the chamber, or to the vacuum reservoir 24 for deflating the chamber. The valves within unit 22 are preferably solenoid valves controlled by the CPU via the pneumatic control module 3.

Pneumatic control module 3 includes pressure sensors with signal conditioning circuitry (amplification and filtration), and solenoid relays. The pressure sensors (e.g., MPX2050, Motorola, USA) measure the pressure in the pneumatic chambers of the pulsating pressure chamber unit 21. The sensor outputs are amplified and low-pass filtered (3dB at 40Hz), and then interfaced to the CPU 8. The solenoid relays within module 3 control the inflation/deflation valves 22 to achieve the required time-pattern of pressure in the pressure chambers of the pressure chamber unit 21.

The blood pressure module 4 measures the arterial blood pressure non-invasively by the sphygmomanometry (Riva-Rocci) method, or by an equivalent method. The blood flow in the peripheral organ of the subject, e.g., a limb, is transiently occluded by the inflation of an occluding cuff 41 surrounding the limb (or other organ). The inflation/deflation of the cuff is effected by a unit 42 under the control of the pneumatic control module 3. The pressure in the cuff is slowly reduced, and the breakthrough of blood through the cuff, which occurs once the arterial blood pressure is larger than the cuff pressure, is identified by the auscultatory method by means of Korotkoff sound identification by a microphone 43. It will be appreciated, however, that the blood pressure could be measured in other manners, e.g., the oscillometric method, by the identification of small pressure pulsations in the cuff, by a Doppler sensor, tonometer, etc. The standard measurement of the systolic and diastolic pressure is enhanced by using the Rodbard method. The resulted arterial blood pressure was demonstrated to be an approximation of the left-ventricular blood pressure.

The vascular flow measurement module 5 measures the flow in a large artery, such as the aorta, non-invasively by standard equipment, such as a commercial Echo-Doppler system (e.g., Sonos 1000 Hewlett-Packard, USA), or a chest impedance

equipment (e.g., CDDP system, BoMED, California, USA). The measured signal may be directly acquired from the Doppler measurement apparatus (e.g., as an analog output of the velocity wave as supplied by a standard vascular Doppler device [e.g., the HD-207, Hadeco, Japan]), or it may be subject to further processing before it is acquired by the data-acquisition board via the Doppler conditioning module 6.

The velocity of the flowing blood is represented as a frequency shift of the ultrasonic wave as sensed by the Doppler sensor in module 5. This Doppler shift is measured by module 6 according to various known methods, such as analog signal analysis (e.g., by frequency-to-voltage conversion, zero-crossing counting), or digital signal analysis (e.g., fast Fourier transform algorithm), as commonly applied in commercial cardiologic Echo-Doppler apparatus.

The measured flow waves are used to calculate ventricular volumes as a function of time. However, instead of measuring flow rates the apparatus can be interfaced with commercial equipment for direct measurement of ventricular volumes such as a nuclear medicine gamma camera system (e.g., Apex system, Elscint, Israel), or new versions of echo-cardiographs which enable the on-line, automatic calculation and display of ventricular volume (e.g., Sonos 1500 with Acoustic Quantification, Hewlett-Packard, USA).

The electrocardiogram (ECG) measurement module 7 may be a standard ECG medical instrumentation which measures, preferably non-invasively, the electrical activity of the subject's heart. It normally contains a set of four electrodes which are applied to the subject's chest, and electronic circuitry which amplify and filter the signal.

The central processing unit CPU 8 may be a standard microcomputer, e.g., an IBM-compatible AT486 personal computer. It is used to control the operation of the above-described modules, to acquire data from the system sensors, to display the measured signals in real time in its display 8c, to analyze the measured data, and to make the various calculations, all as more particularly described below. In a typical configuration, it may include a microprocessor such as Intel 486, 8MB of RAM memory, 130 MB hard disc, a floppy disc, a high resolution screen, and a screen adaptor.

The database 8b includes the subject identification data, the measured data and the results of the various calculations to be made as to be described below. These are saved in the system database 8b and are edited to produce the measurement report. The database 8b can be based on any standard software, e.g., Excel (Microsoft, USA), or on custom made software.

The data processor system including the CPU 8 also includes a real time module which acquires the measured signals via the data acquisition board 9, processes them in real time (e.g., calibration to physical units), records them in the CPU memory, and displays them. In addition to data acquisition, the real time module controls the pneumatic system of the pneumatic module 2 which applies the external pressure pulsations on the subject's body.

The illustrated data processor system including the CPU 8 further includes an analysis module, which measures the various signals involved, including the R-wave trigger of the ECG signal from module 7, the pulsating pressure applied by the pneumatic module 2, the flow rate as sensed by the Doppler modules 5 and 6, and the blood pressure sensed by the blood pressure module 4. The pressure and flow rates are averaged and numerically processed to yield pressure-volume loops and various other indices of the cardiovascular system, during the operation of the system, as described more particularly below.

Fig. 2 illustrates the determinants of the cardiovascular system performance. Thus, as briefly described earlier and as more particularly illustrated in Fig. 2, the global performance of the cardiovascular system is based on four main determinants:

- (a) myocardial contractility, namely the ability of the heart muscle elements to contract and create a force;
- (b) initial loading, or ventricular preload, namely the initial length (or stress) of the muscular fibers, and is dependent on the state of filling of the heart;
- (c) vascular load, or afterload, namely the load against which the heart acts; and
- (d) chronotropy, or heart rate, namely the number of cycles of heart contraction per unit time.

The present invention is mainly directed to assessing the first of the above determinants, myocardial contractility; this is relatively independent of the other determinants. More particularly, the present invention is primarily directed to determining, in accordance with a non-invasive technique, the ventricular elastance or end-systolic elastance (Ees) and the preload recruitable stroke work (PRSW), which have been previously suggested as an index of myocardial contractility.

Following is a description of one manner of using the apparatus illustrated in Fig. 1 for assessing the cardiovascular performance of a subject in accordance with the present invention.

The pneumatic module 2, and particularly its pulsating chamber 21, is used for applying external pressure pulsations on a peripheral organ of the subject (e.g., on the lower limbs and/or on the abdomen) of a sufficiently high level to alter ventricular loading. These external pressure pulsations

are applied periodically once for every two or more heart cycles, as synchronized by the R-wave of the ECG signal. The ECG signal is illustrated by curve A in Fig. 3, and the external pressure pulsations are illustrated by curve B. It will be seen that the external pressure pulsations are applied for every other heart cardiac cycle, and for the complete respective cycle; however, such pulsations may be applied for several consecutive cycles, as illustrated in Fig. 8. The hemodynamic effect of the external pressure pulsations depends on the magnitude and the timing of the pulsations. In the above-described embodiments, relatively high magnitude pressure pulsations (of 150-180 mm Hg) are applied during one cycle and are released during the following cycle.

Each external high pressure pulsation results in an increased arterial pressure which impedes the ventricular ejection. The ventricular ejection during such a higher level of arterial pressure results in higher left-ventricular pressure and lower flow and stroke volume, as compared to the ventricular ejection during a lower level of arterial pressure. Thus, in the heart cardiac cycles during which the external pressure pulsations are applied, the arterial blood pressure is high and the aortic flow rate is low as compared to the heart cardiac cycles during which the external pressure pulsations are now not applied. The foregoing are illustrated by curves C and D in Fig. 3.

Fig. 4A illustrates the aortic flow both during the absence of the external pressure pulsations (amplitudes E_1) and during the presence of the external pressure pulsations (amplitudes E_2). The flow rate is measured by the Doppler modules 5 and 6 in Fig. 1.

The measurement process continues for about 30-60 seconds. This normally spans 35-70 cycles during rest and up to 90-180 cycles during maximal stress (e.g., exercise stress test). The amplitudes E_1 and E_2 are averaged separately for the complete measurement period to yield two average flow waves F_1 , F_2 , respectively, as shown in Fig. 4B. The average flow waves are then integrated in the time domain to yield the ejected volume of the left ventricle as a function of time.

The end-diastolic volume may be measured by an external apparatus, e.g., a gamma-camera or an Echo-Doppler. The ventricular volume as a function of time during ejection can then be calculated by subtracting the ejected volume from the end-diastolic volume.

The foregoing is more particularly illustrated in Fig. 4C, wherein curve G illustrates the ventricular volume as a function of time, points EDV_1 and EDV_2 represent the end diastolic volume, and points ESV_1 and ESV_2 represent the end-systolic volume.

Figs. 5A and 5B illustrate a known non-invasive method for reconstructing the rising part of an arterial pressure wave by using an occluding cuff, such as cuff 42 in the blood pressure module 4. Thus, the pressure in the occluding cuff is measured at the time of blood breakthrough across the occlusion. The breakthrough of blood, which occurs once the arterial pressure exceeds the pressure in the occluding cuff, may be determined by various methods and sensors; in the example illustrated in Fig. 5A, this is determined by the Korotkoff sounds, as sensed by microphone 43 in Fig. 4. The time delay between the time of heart contraction, as determined by the R-wave of the ECG, and the time of blood breakthrough is calculated, and the cuff pressure versus time delay is plotted. This results in a reconstructed upstroke portion of the arterial pressure wave, as shown in Fig. 5B.

Figs. 6A and 6B illustrate the foregoing technique for reconstructing the rising part of the arterial pressure waves during the heart cardiac cycles wherein the external pressure pulsations are applied, and also during the heart cardiac cycles wherein the external pressure pulsations are not applied. The two pressure waves so reconstructed, as shown in Fig. 6B, may then be extrapolated to the end-systolic pressure point according to known techniques. The time of end-systole (end ejection) may be determined from the average flow waves of Fig. 4B.

Two pressure-volume loops can be reconstructed from the pressure curves of Fig. 6B and the volume curves of Fig. 4C. Thus, the reconstructed pressure wave (Fig. 6B) and the calculated volume waves (Fig. 4C) are aligned together in time, as shown in Fig. 7A. Couples of pressure and volume data points are taken at sequential times and are used to construct the pressure-volume loop illustrated in Fig. 7B.

The pressure-volume loops of Fig. 7B can be used to derive the end-systolic pressure-volume relation, ESPVR, as also shown in Fig. 7B. The ESPVR is determined during (a) the cardiac cycles in which the external pressure pulsations are applied, and (b) the cardiac cycles during which the external pressure pulsations are not applied. For this purpose, the data processor: (1) produces a measurement (Va) of the volume of the heart left ventricle as a function of time during the cardiac cycles (a), and a corresponding measurement (Vb) during the cardiac cycles (b); (2) constructs from the measurements of the arterial pressure at least a portion (Pa) of the approximate left-ventricular blood pressure wave during the cardiac cycles (a) and a corresponding portion (Pb) of the pressure wave during the cardiac cycles (b); (3) determines from the measurements Pa, Va and Pb, Vb (Fig. 7A) the relations $P(V)a$ and $P(V)b$ (Fig. 7B) of

ventricular blood pressure with respect to ventricular volume during the heart cardiac cycles (a) and (b), respectively; and (4) determines from the relations $P(V)a$ and $P(V)b$, the ESPVR during the heart cardiac cycles (a) and (b), respectively. The data processor produces measurements (Va) and (Vb) by measuring the average aortic flow during the heart cardiac cycles (a) and (b), and by integrating the average aortic flows over the plurality of heart cardiac cycles or by getting direct measurement of ventricular volumes from an external apparatus. The slope of the ESPVR may then be determined. This slope provides a well accepted approximation of the ventricular elastance of the subject.

Figs. 8 and 9 illustrate a second preferred embodiment wherein low magnitude pressure pulsations (50-80 mm Hg) are applied during a plurality (N_1) cardiac cycles over the abdomen and are released during a plurality (N_2) of the following cardiac cycles. The pressure pulsation increases the abdominal pressure and occludes transiently the inferior vena-cava. This maneuver reduces the venous return to the right ventricle, which reduces the ventricular volume and pressure. This direct effect on the right ventricle is transmitted to the left ventricle and yields periodically changing left ventricular volumes, ejection flows, and pressures as illustrated in Fig. 8. The flows, volumes and pressures are measured similarly as described earlier for pressure pulsation of one cardiac cycle duration. It should be noted, however, that more than two pressure-volume loops are acquired, as illustrated in Fig. 9.

It will thus be seen that the illustrated apparatus and method can be used for the non-invasive measurement of CVS indices in general, and the ventricular elastance in particular. The illustrated apparatus and method can also be used to assess the CVS status in patients with various heart diseases and clinical states, e.g., ischemic heart disease, congestive heart failure, dilated cardiomyopathy. The apparatus and method can also be used to monitor the effects of therapy, e.g., medications and rehabilitation activity.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the scope of each element identified by way of example by such reference signs.

Claims

1. A method of assessing the cardiovascular performance of a subject, comprising: applying periodically, in synchronism with every n^{th}

heart cardiac cycle wherein "n" is at least two, external pressure pulsations on a peripheral organ of the subject sufficient to alter ventricular loading; acquiring data representative of the ventricular pressure, and data representative of the ventricular volume, of the subject's heart over a plurality of heart cardiac cycles; and utilizing said data for assessing the cardiovascular performance of the subject.

2. The method according to Claim 1, wherein said external pressure pulsations are applied during every other heart cardiac cycle, such that $n = 2$.

3. The method according to Claim 1, wherein said external pressure pulsations are applied during a plurality (N_1) cardiac cycles, and are released during a plurality (N_2) cardiac cycles, such that $n = N_1 + N_2$.

4. The method according to Claim 1, wherein said acquired data is utilized for assessing the cardiovascular performance of the subject by: determining the end systolic pressure volume relation (ESPVR) of the subject's heart during (a) the heart cardiac cycles in which said external pressure pulsations are applied, and (b) the heart cardiac cycles in which the external pressure pulsations are not applied; and determining the slope of the ESPVR during the heart cardiac cycles (a) and (b) to thereby provide an approximation of the ventricular elastance of the subject's heart.

5. The method according to Claim 1, wherein said pressure applicator is a pneumatic device.

6. Apparatus for assessing the cardiovascular performance of a subject, comprising: a pressure applicator and a control therefor for applying periodically, in synchronism with every n^{th} heart cardiac cycle wherein "n" is at least two, external pulsations on a peripheral organ of the subject sufficient to alter ventricular loading; sensors for sensing parameters of the subject varying with the left-ventricular blood pressure and the left-ventricular volume of the subject's heart, and for producing outputs corresponding to said sensed conditions; and a data processor for processing the outputs of said sensors and for producing data representative of the left-ventricular blood pressure and the ventricular volume of the subject's heart over a plurality of heart cardiac cycles and useful in assessing the cardiovascular performance of the subject.

7. The apparatus according to Claim 6, wherein said data processor processes the outputs of said sensors: to determine the end systolic pressure volume relation (ESPVR) of the subject's heart during (a) the heart cardiac cycles in which said external pressure pulsations are applied, and (b) the cardiac cycles during which the external pressure pulsations are not applied; and also to determine the slope of the ESPVR during the heart cardiac cycles (a) and (b), to thereby provide an approximation of the ventricular elastance of the subject's heart.

8. The apparatus according to Claim 7, wherein said data processor: produces a measurement (V_a) of the volume of the heart left ventricle as a function of time during said cardiac cycles (a), and a corresponding measurement (V_b) during the cardiac cycles (b); constructs from said left-ventricular blood pressure data at least a portion (P_a) of the pressure wave during the cardiac cycles (a) and a corresponding portion (P_b) of the pressure wave during the cardiac cycles (b); determines from said measurements P_a , V_a and P_b , V_b the relations $P(V)_a$ and $P(V)_b$ of left-ventricular blood pressure with respect to ventricular volume during the heart cardiac cycles (a) and (b), respectively; and determines from said relations $P(V)_a$ and $P(V)_b$, the ESPVR during the heart cardiac cycles (a) and (b), respectively.

9. The apparatus according to Claim 8, wherein said data processor produces measurements (V_a) and (V_b) by measuring the average aortic flow during said heart cardiac cycles (a) and (b), and by integrating the average aortic flows over the plurality of heart cardiac cycles.

10. The apparatus according to Claim 6, wherein said pressure applicator is a pneumatic device.

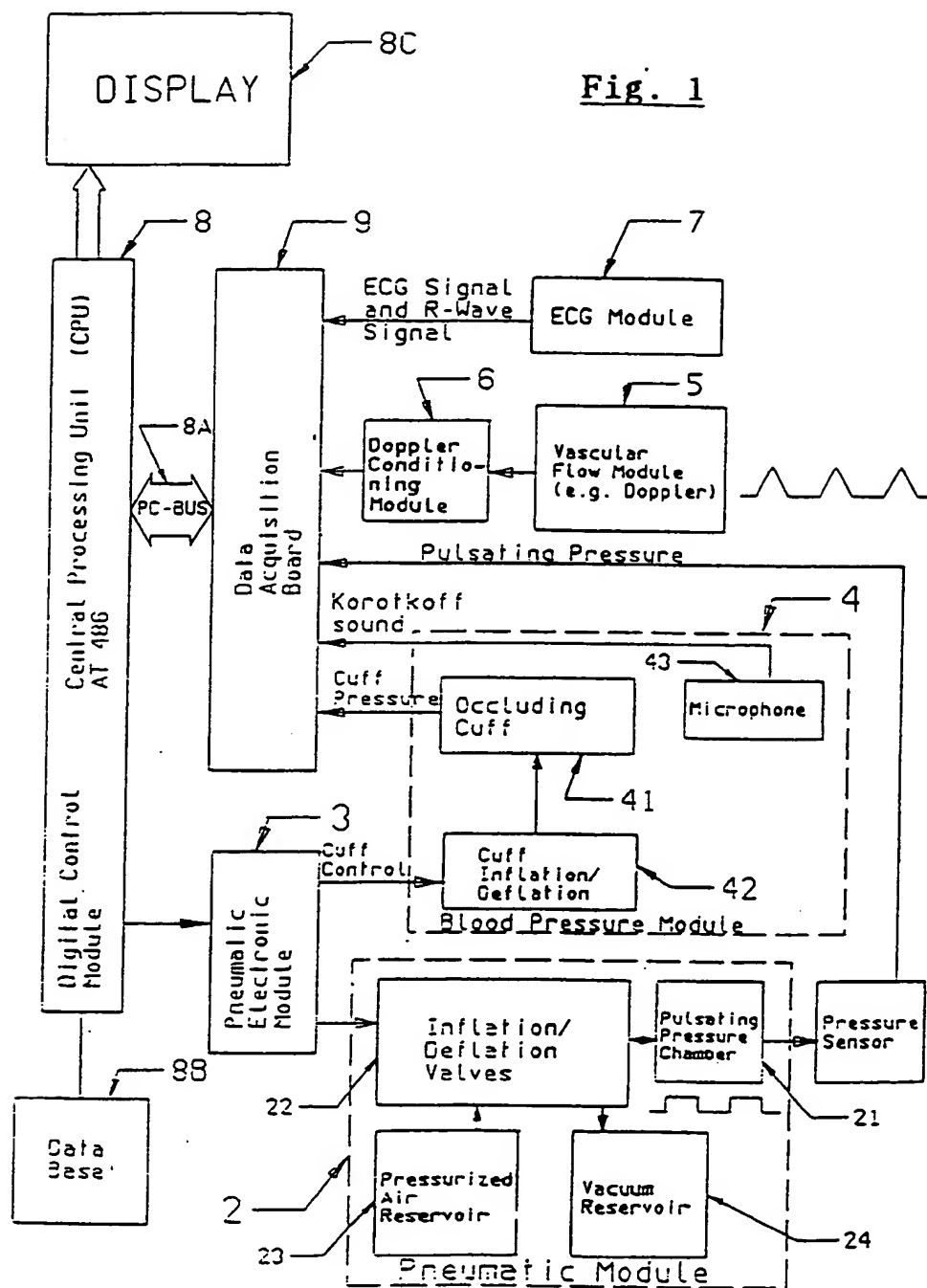


Fig. 2

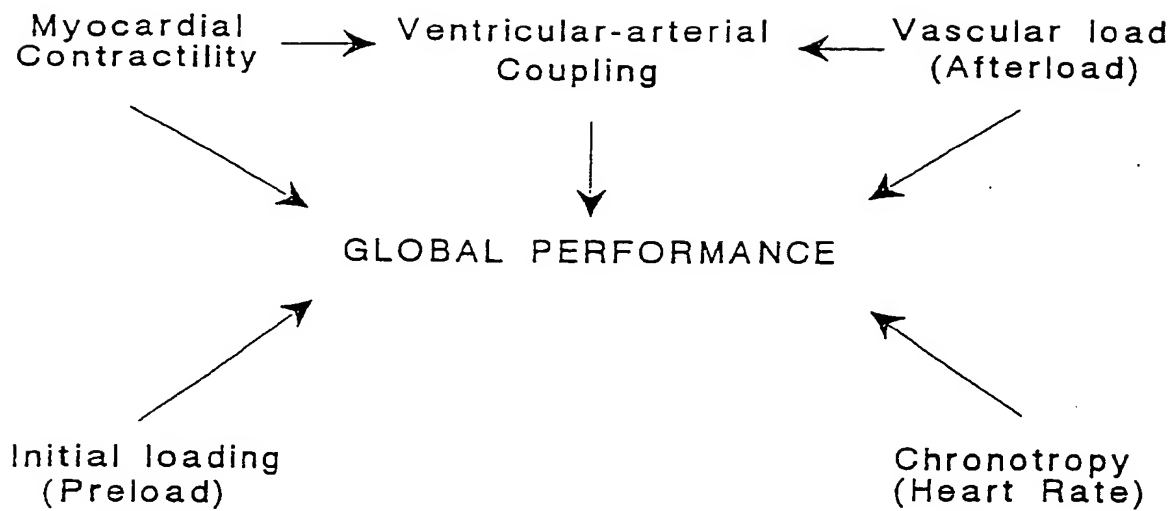


Fig. 3

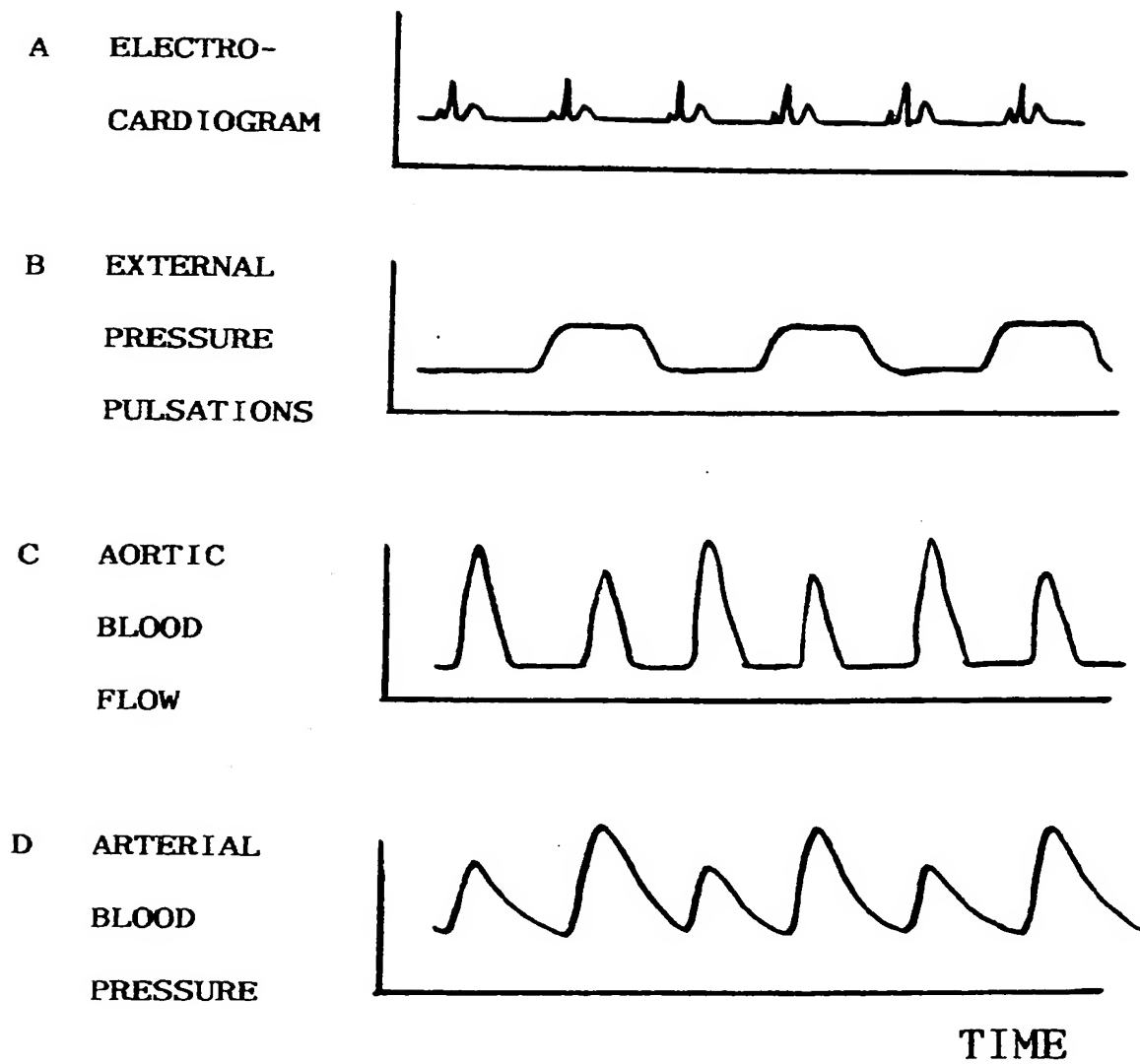


Fig. 4A

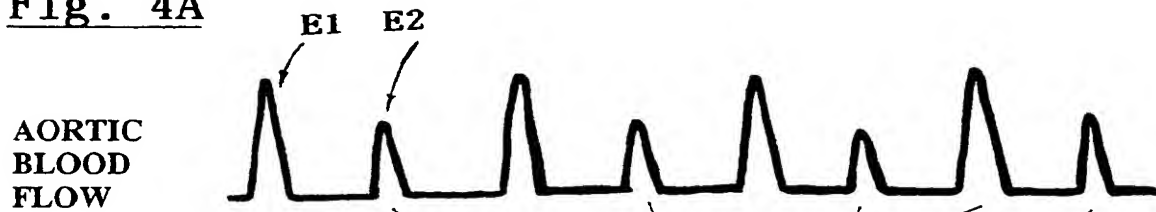


Fig. 4B

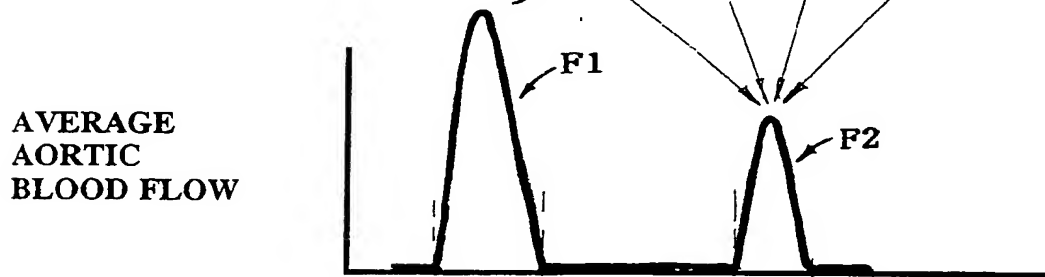


Fig. 4C

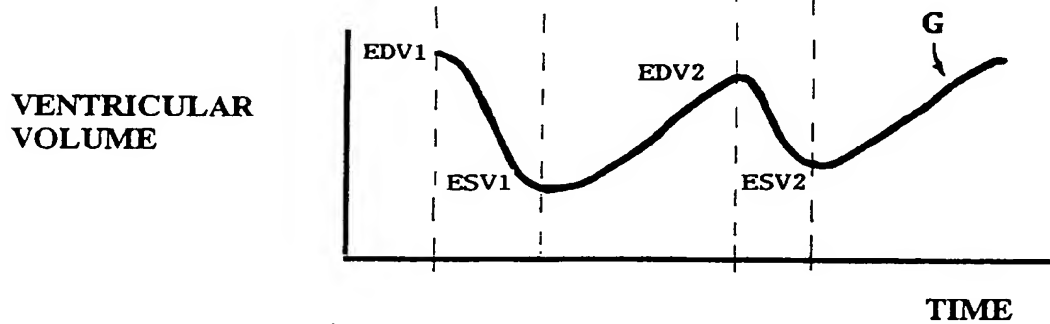


Fig. 5A

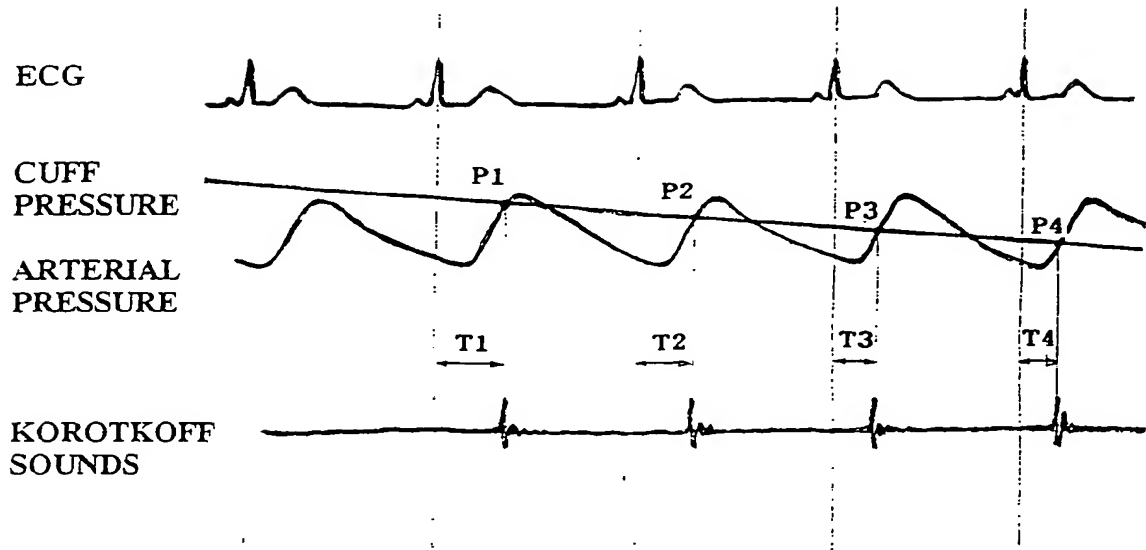


Fig. 5B

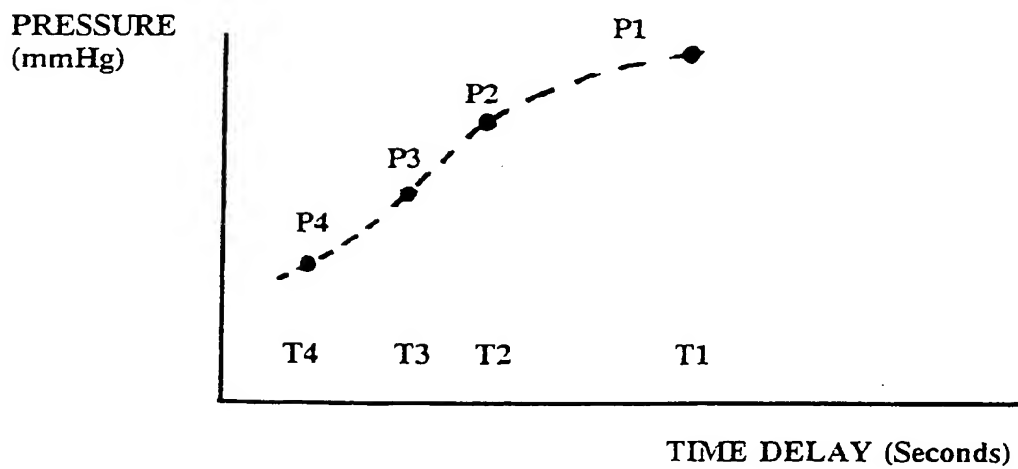


Fig. 6A



Fig. 6B

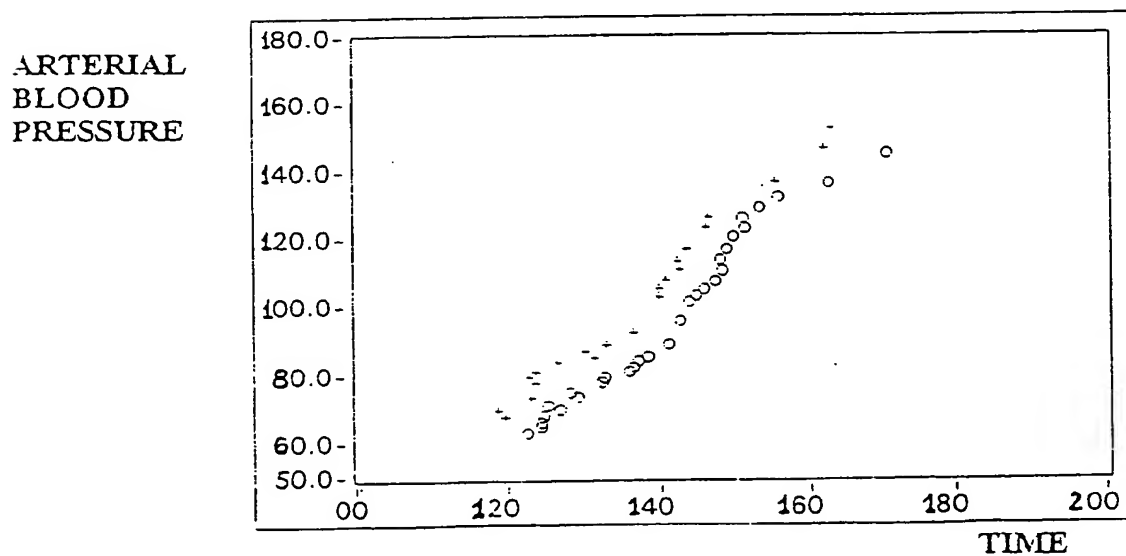


Fig. 7A

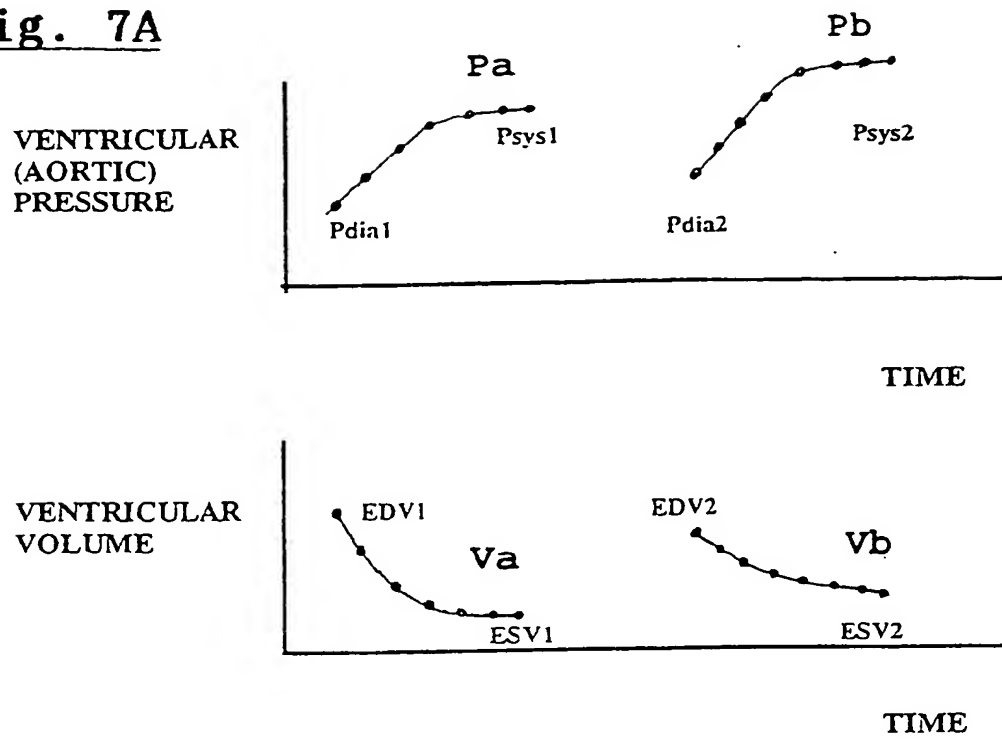


Fig. 7B

$$E_{max} = \text{Slope of ESPVR} = \frac{P_{es2} - P_{es1}}{ESV2 - ESV1}$$

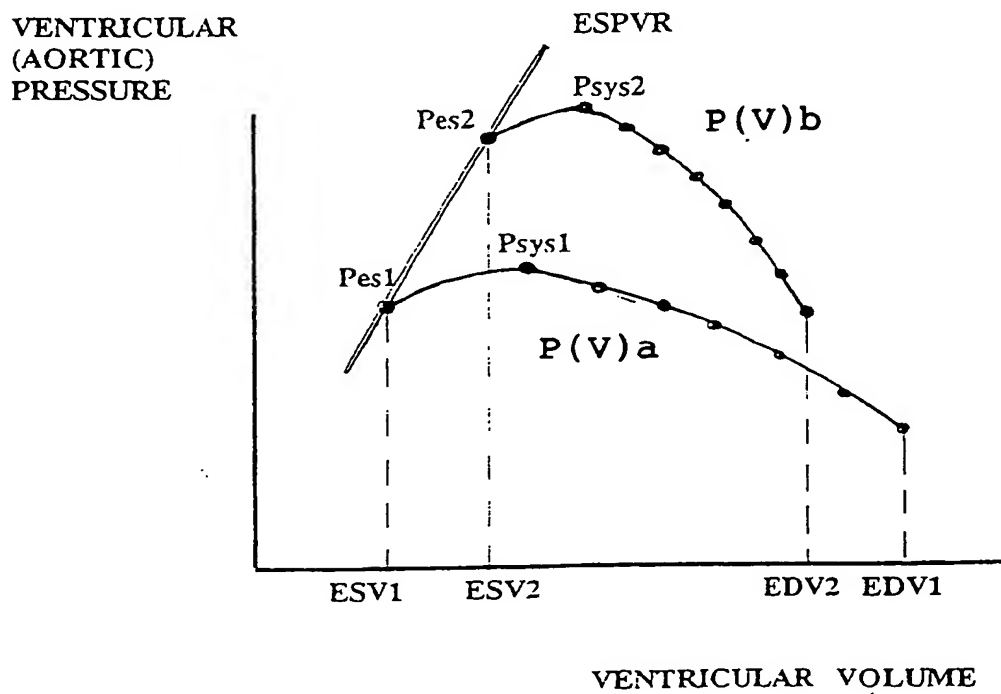


Fig. 8

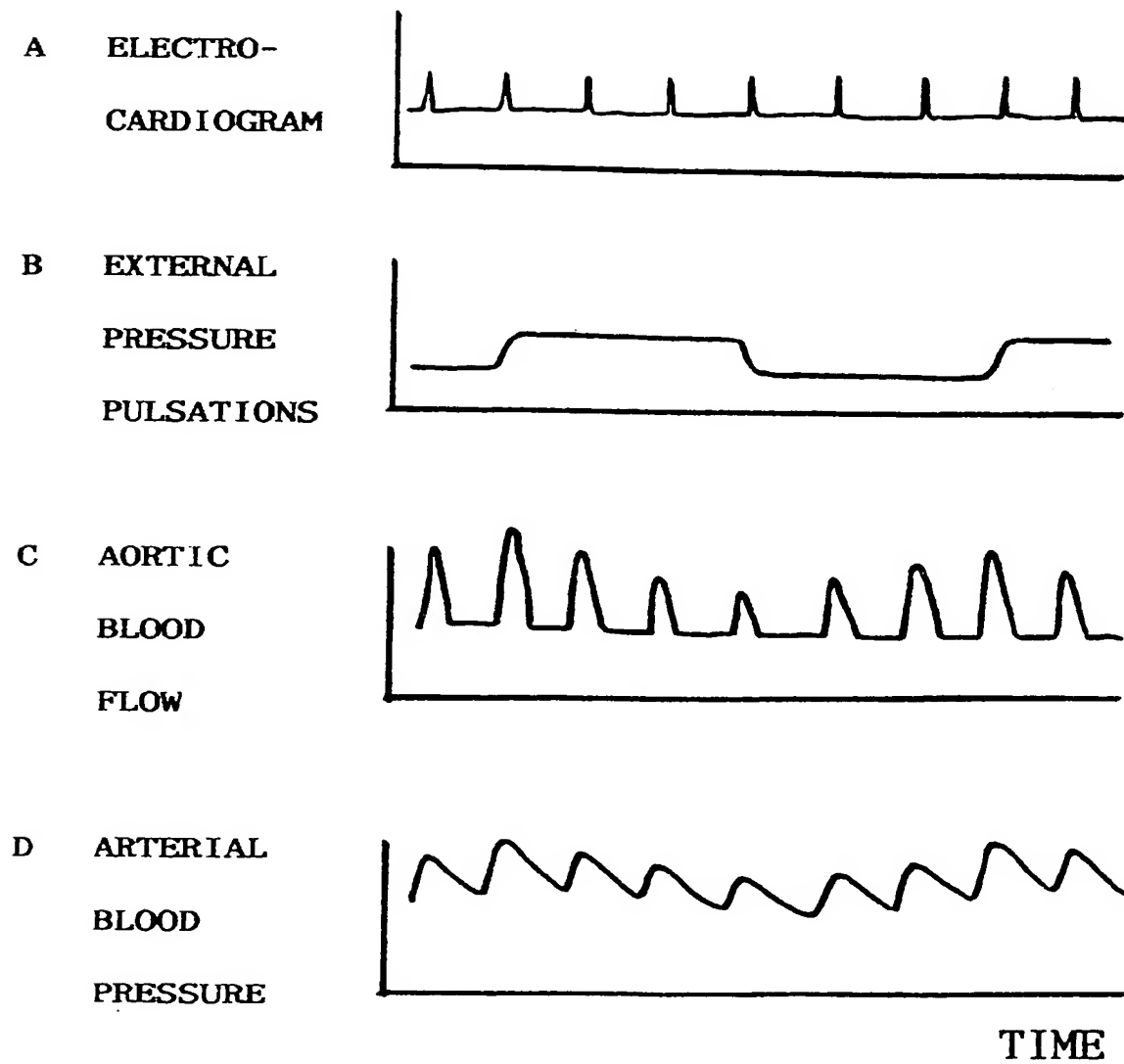
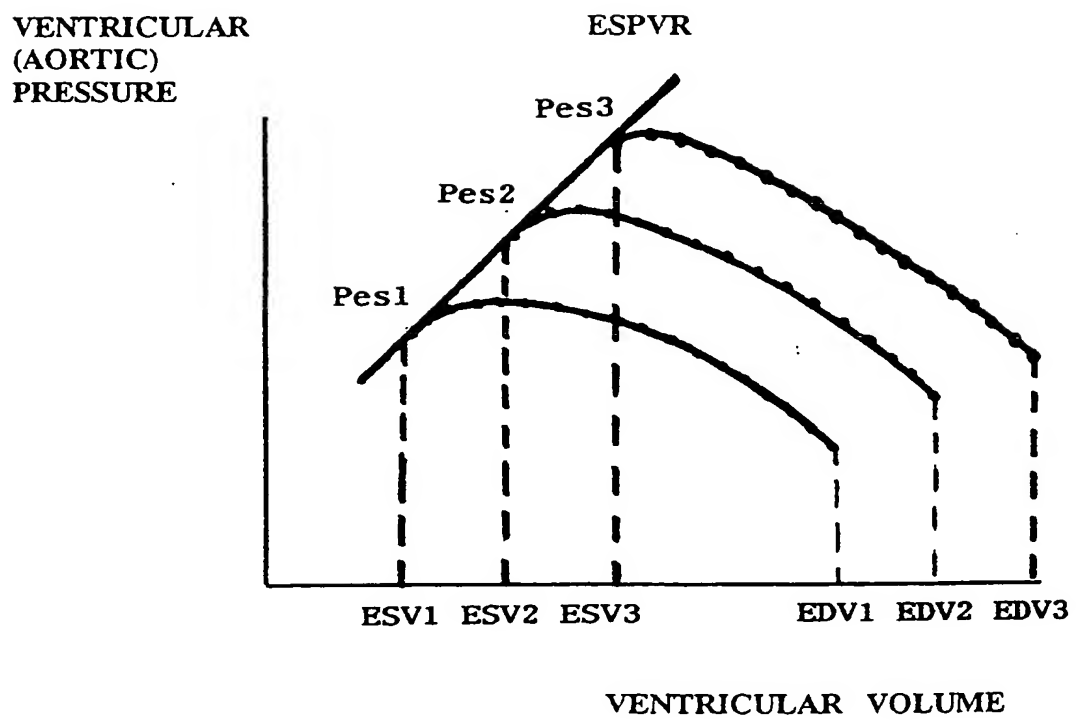


Fig. 9





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 11 7410

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION
X	EP-A-0 420 085 (ATP ADVANCED TECHNOLOGIES LTD.)	1,5,10	A61B5/029
Y	* column 7, line 31 - column 18, line 3 *	6	A61B5/0205
A	* figures 1-10 *	2,3,8,9	A61B5/0285
	---		A61B8/06
Y	WO-A-89 07414 (VASCULAR SURGICAL FORUM)	6	
X	* page 3, line 27 - page 4, line 12 *	5,10	
	* page 7, line 1 - page 8, line 13; figures 1,2 *		

A	WO-A-91 13589 (PRECISION DIAGNOSTICS, INC.)	1	
	* page 13, line 5 - page 17, line 21; figures 1,2 *		

A	US-A-4 137 910 (D.H.MURPHY)	1	
	* column 1, line 9 - column 2, line 34 *		
	* column 2, line 62 - column 3, line 45; figure 1 *		

			TECHNICAL FIELDS SEARCHED (Int. CL. 6)
			A61B
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 16 January 1995	Examiner Weihs, J
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	